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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
SOUTHWEST REGION

Office of the Regional
Food and Drug Director
7920 Elmbrook Drive, Suite 102
Dallas, TX 75247-4982
TELEPHONE: 214-655-8100
FACSIMILE: 214-655-8130

WARNING LETTER

July 27, 1997

Debbie Storie
Owner
Tropical Tan
1900 Rock Road
Desoto, MO 63020

Dear Ms. Storie:

The inspection of your tanning facility, Tropical Tan located at 1900 Rock Road, Desoto, MO 63020, on June 25, 1997, by investigator Dennis Butcher revealed serious violations of the Federal Food, Drug and Cosmetic Act (the Act). The investigator documented significant items of noncompliance with the Federal Performance Standard for Sunlamp Products as prescribed in Title 21, Code of Federal Regulations, Part 1040. 20 (21 CFR 1040.20) in conjunction with a tanning booth in operation at your facility. The inspection indicated the noncompliances for Fitness To Go, model Odyssey Tan 4000, s/n 00147.

The inspection revealed that the tanning booth was misbranded within the meaning of Section 502(f) of the Act. There was no user instruction manual or documentation of lamp compatibility available for this tanning booth to provide adequate directions for use in such manner as necessary for the protection of users against potentially harmful exposure to ultraviolet radiation [21 CFR 1040.20(e)(1)]. In addition, this tanning booth had no labeling containing the danger/warning statement as required by 21 CFR 1040.20(d). The maximum timer interval for this booth may not exceed the manufacturer's recommended maximum exposure time [21 CFR 1040.20(c)].

The above identification of violations is not intended to be an all-inclusive list of deficiencies regarding sunlamp products at your firm. It is your responsibility to assure that electronic sunlamp products are maintained so that they continue to comply with the provisions of the Act. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure, injunction, and/or civil money penalties, without further notice.

You should notify this office in writing 15 working days of receipt of this letter, of specific steps you have taken to correct these violations. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Your reply should be directed to Deborah M. McGee, Radiation Specialist, U.S. Food and Drug Administration, 7920 Elmbrook Drive, Suite 102, Dallas, Texas 75247-4982, telephone (214) 655-8100, ext. 138.

Sincerely,

B. Belinda Collins
Regional Radiological Health Representative
Southwest Region

DM:dm